Paper No. 32

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte KENNETH F. BUECHLER and PAUL H. MCPHERSON

Appeal No. 2001-1589
Application No. 08/769,077

HEARD: July 9, 2002

Before WINTERS, SCHEINER and ADAMS, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1-8, 10 and 18. Claim 9, also pending in the application, is not subject to rejection. Claims 11-17 have been canceled.

Claim 1 is representative of the subject matter on appeal:

1. A method for reducing the ability of troponin I and troponin T in a patient sample suspected of containing troponin from damaged heart muscle to bind to a surface, said method comprising the steps of:

contacting a sample obtained from a patient with a surface, and prior to, after, or during said contacting,

adding exogenous troponin C to the surface or to the patient sample under conditions in which troponin C will bind to said troponin I and/or troponin T from the patient sample and reduce binding of said troponin I and/or troponin T to said surface, wherein said exogenous troponin C is not bound to said surface and is not labeled.

The references relied on by the examiner are:

Larue & Marquet (Larue)	GB 2,275,774	Sep. 7, 1994
Wicks (et al.)	WO 94/27156	Nov. 24, 1994

Claims 1-6, 8 and 10 stand rejected under 35 U.S.C. § 102(a) as anticipated by Larue, while claims 7 and 18 stand rejected under 35 U.S.C. § 103 as unpatentable over Larue and Wicks. We reverse both of these rejections.

BACKGROUND

> The troponin complex in muscle is comprised of troponin I, C and T . . . [which] exist as various tissue specific isoforms. Troponin C exists as two isoforms, one from cardiac and slow-twitch muscle and one from fast-twitch muscle. Troponin I and T are expressed as different isoforms in slow-twitch, fast-twitch and cardiac muscle . . . The unique cardiac isoforms of troponin I and T allow them to be distinguished immunologically from the other troponins of skeletal muscle. Therefore, the release into the blood of troponin I and T from damaged heart muscle has been related to cases of unstable angina and myocardial infarction . . . (Specification, pages 3 and 4).

According to appellants, "[p]rior to the instant invention, troponins I and T were believed to be 'unstable' in aqueous solutions." Brief, page 6. "As a result of this 'instability,' assays for troponin I and/or T in patient samples could report falsely low concentrations of troponin proteins, resulting in a falsely negative diagnosis for heart damage. It was unrecognized that a major source of this 'instability' is the propensity of troponins I and T to adsorb tenaciously to glass and other surfaces." Id. "However, when bound to troponin C . . . the absorptive characteristics of of troponin I and T may be dramatically reduced." Specification, page 44.

The present invention is based on the premise that pretreating a patient sample with exogenous troponin C will reduce the incidence of inaccurate assay results by reducing the tendency of troponin I and troponin T in the patient sample to non-specifically bind various assay surfaces (e.g., glass, plastic, lipsomes, other blood components, etc.). Specification, page 43, line 28 through page 44, line 3.

DISCUSSION

Claim 1, which represents the invention in its broadest aspect, requires contacting a patient sample (suspected of containing troponin from damaged heart muscle) with exogenous troponin C, and a "surface." There are two provisos regarding the exogenous troponin C in the claims: it cannot be labeled, and it cannot be bound to the surface. In addition, there are four possible scenarios for the contacting step(s): (1) the troponin C and the patient sample can be contacted initially, and then with the surface; (2) the troponin C and the surface can be contacted initially, and then with the patient sample; (3) the patient sample and the surface can be contacted initially, and then with the troponin C; and finally (4) the patient sample, the surface and the troponin C can be contacted simultaneously.

The examiner maintains that claims 1-6, 8 and 10 are anticipated by Larue, and that claims 7 and 18 are unpatentable over the combined teachings of Larue and Wicks. The examiner's interpretation of Larue's teachings is central to both rejections, so we will discuss them together.

Larue describes calibration reagents for troponin immunoassays, prepared by adding a known amount of troponin I or troponin T, obtained from isolated human heart, to a buffer (which may comprise normal human plasma). In addition, troponin C is included in the calibration reagent to stabilize the troponin I or T. Page 2, lines 20-29; page 3, lines 4-10 and 32-33; and page 4, lines 3-4. The calibration reagent is intended for use as a standard in serum or blood plasma troponin immunoassays, to be run in parallel with a sample containing an unknown amount of troponin I or T. Page 3, lines 20-29 and page 5, lines 12-17.

The examiner bears the burden of establishing a prima facie case of anticipation or obviousness. See In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990); In re Fritch, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992). In our view, that burden has not been carried here. At issue is the examiner's assertion that "the [troponin I] of the standardized solution is obtained from a human heart which means that the standardized solution comprising [troponin I] is from a patient." Answer, page 5. Appellants argue that Larue does not anticipate the present invention because "neither an isolated human heart, nor a dead human, can be considered a patient," and "[t]herefore, the troponin used in the standard solution of [Larue] is not a 'patient sample.'" Brief, page 12. Further, "the 'normal human plasma' used to dissolve the troponin I or T to make the standard solution of [Larue] cannot be 'a sample suspected of containing troponin from a damaged heart muscle,'" either. Rather, it is "plasma that is not suspected of containing troponin from damaged heart muscle." Id. We agree with appellants.

The specification does not explicitly describe "a patient" or "a patient sample," but it is readily apparent from the context in which patients and patient samples are mentioned that the term does not, as the examiner insists, encompass a cadaver or an isolated human heart. Merely by way of example, the specification (pages 17-19) teaches that:

> The assays taught herein provide for the analysis of release patterns which may allow the physician to diagnose a specific heart failure, for example, unstable angina as compared to myocardial infarction or to determine the time that an infarction occurred . . . Generally, in hospital emergency departments which admit patients believed to have had a myocardial infarction, a blood sample from the individual will be obtained again in an hour or two if the first result is negative. In this example, the patient . . . would not be treated and would continue to accrue damaged heart muscle during the time before a second sample was analyzed . . .

> [T]he rise or fall of the troponin I or T concentration in a patient's blood over time as determined by analyzing blood samples drawn at several different times might be used to diagnose the dynamic condition of the heart, for example, to determined whether the damaged heart is improving with therapy or continuing to deteriorate.

"Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim." Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997). Here, Larue does not meet the claim limitation requiring contacting a patient sample with troponin C, and therefore does not anticipate the instant claims. Accordingly, the rejection of claims 1-6, 8 and 10 under 35 U.S.C. § 102(a) is reversed.

With respect to the rejection of claims 7 and 18 over the combined disclosures of Larue and Wicks, we agree with appellants that Wicks does not cure the underlying deficiency in Larue, and the examiner has not established a prima facie case of obviousness. Accordingly, the rejection of claims 7 and 18 under 35 U.S.C. § 103 is reversed as well.

REVERSED

Sherman D. Winters Administrative Patent Judge	)
Toni R. Scheiner Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
Donald E. Adams Administrative Patent Judge	)

Richard J. Warburg
Foley & Lardner
402 W. Broadway, 23rd Floor
San Diego, CA 92101-3542